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| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/802,030

Applicant(s)

BENOIT ET AL.

Examiner

TERRA C. GIBBS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-15 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 8 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed November 29, 2007.

Claims 1-21 are pending in the instant application.

Claims 1-6 and 8 have been amended.

Claims 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 8, 2006.

Applicant is reminded that the Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Accordingly, claims 1-19 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed October 4, 2007, claims 1-19 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is withdrawn** in view of Applicant's Arguments filed

November 29, 2007. Specifically, the Examiner agrees that, in view of the teachings of GenBank Accession No. AF131884 (Aihara) and *Parks*, the instant application has inherent and implicit support for the limitation, "provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO:2" as recited in the instant claims.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed October 4, 2007, claims 1-6, 15, and 17-19 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65924 ('924). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed October 4, 2007. It is noted that the Examiner inadvertently omitted claims 7 and 9-14 from this rejection. Therefore, claims 1-7, 9-15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65924 ('924). Claims 7 and 9-14 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations of an expression cassette comprising a sequence encoding a protein or an RNA of therapeutic interest operably linked to the polynucleotide according to claim 1; wherein the protein or RNA of therapeutic interest induces angiogenesis; wherein the protein or RNA of therapeutic interest is a cytokine; wherein the protein is an immunosuppressive protein; wherein the immunosuppressive protein is IL-2; wherein the protein reduces hypoxia; and wherein the protein that reduces hypoxia is catalase.

The '924 application discloses and claims an isolated population of polynucleotides comprising or corresponding to polynucleotides corresponding to at least one polynucleotide shown in Table 1 and their respective complements (see Table

1 of '924 and claim 1). It is noted that at least one of the polynucleotides of the '924 application are fully complementary to nucleotides 752-761 of SEQ ID NO:7 of the instant invention and thus will hybridize with a sequence of SEQ ID NOs: 3-7 of the instant invention. Further, another of the polynucleotides of the '924 WO document is fully complementary to nucleotides 294-303 of SEQ ID NO:7 of the instant invention and thus will hybridize with a sequence of SEQ ID NOs: 3-7 of the instant invention. Further, another of the polynucleotides of the '924 WO document is fully complementary to nucleotides 734-743 of SEQ ID NO:7 of the instant invention and thus will hybridize with a sequence of SEQ ID NOs: 3-7 of the instant invention. Since the polynucleotides of the '924 application are fully complementary to SEQ ID NO:7 of the instant invention, given this high degree of similarity, the polynucleotides disclosed by the '924 application meet the structural limitations of the claimed invention and would be expected to hybridize after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS with a sequence of SEQ ID NOs: 3-7. It is further noted that the polynucleotide sequences of the '924 application comprise exogenous nucleotide sequences, including sequences encoding a protein or an RNA of therapeutic interest (see page 7, lines 20 and 21 and page 22 lines 28-30, for example). It is further noted that the polynucleotides of the '924 application elicit an immune response (see page 5, lines 2-5, for example). It is finally noted that the polynucleotide sequences of the '924 application comprise a cytokine, IL-12, or catalase (see page 15, lines 17-29 and page 88, for example).

Response to Arguments

In response to this rejection, Applicants firstly argue that the sequences of the '924 application do not anticipate the claimed sequences since the sequences are only identical over a ten base pair region. Applicants contend that accordingly, the full-length sequences of the '924 application do not anticipate the claimed invention because they do not disclose all of the elements of the claims, particularly the claimed function. Specifically, Applicants argue that nothing in the '924 patent suggests that the ten base pair sequences of the '924 application can support the recited function, namely the ability to specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked the polynucleotide. It is for these reasons that Applicants contend that the '924 application does not expressly or inherently disclose all the elements of the claims.

Applicant's arguments and contentions have been fully considered, but are not found persuasive because the polynucleotides of the '924 application meet all the structural limitations of the claims, namely the ability to hybridize to a sequence of SEQ ID NOs: 3-7 after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS. It is noted that the '924 application does not disclose that the polynucleotides of their invention have the ability to specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked the polynucleotide. However, the burden of establishing whether the prior art polynucleotides have the further function of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked the polynucleotide, under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where

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the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the polynucleotides of the '924 application would or would not have the additional functional limitation of specifically inducing expression in cardiac cells *in vivo* of a gene which is operably linked the polynucleotide as instantly claimed.

Applicants secondly argue that the sequences of the '924 application fail to anticipate the claims because they would not hybridize under high stringency conditions. Applicants contend that claim 1 has been amended to recite specific high stringency conditions, where such conditions would not allow a duplex of ten base pairs to hybridize to because the melting temperature of such a duplex is substantially below

65°. It is for these reasons that Applicants contend that the sequences of the '924 application will not hybridize under the recited high stringency conditions and thus do not anticipate the claims.

Applicants argument and contention have been fully considered, but are not found persuasive because it is unclear how Applicants are coming up with the assertion that the melting temperature of the prior art duplex is substantially below 65°. Applicants have made this assertion without any calculation or scientific basis to justify their position. Applicant is reminded that arguments of counsel alone cannot take the place of evidence in the record. See MPEP §2106. Applicant has not provided any evidence that the melting temperature of such a duplex is substantially below 65°. Because claim 1 is drawn to an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragments comprises either of SEQ ID NOs: 3-7 or a sequence that hybridizes after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS to SEQ ID NOs. 3-7, and the prior art meets all the structural limitations of the claims, namely an isolated polynucleotide comprising a sequence that hybridizes after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS to SEQ ID NOs: 3-7, it is the Examiner's position that the aforementioned sequences of the '924 application anticipates the claims.

Regarding Applicants specific argument that the ten base pair sequence will not hybridize under the recited high stringency conditions, this argument has not been found persuasive because given the high degree of complementary between the sequences of the '924 application and isolated polynucleotides of Applicant's invention,

it is the Examiner's position that the aforementioned sequences of the '924 application will hybridize to a sequence of SEQ ID NOs: 3-7, after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS given traditional Watson Crick base pairing.

Therefore, the '924 application anticipates claims 1-7, 9-15, and 17-19.

Conclusion

Since the Examiner did not include claims 7 and 9-14 in the previous 35 U.S.C. 102(b) rejection mailed October 4, 2007, the instant Office Action is a non-final Office Action.

Claims 8 and 16 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten to remove nonelected subject matter and rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claims 8 and 16 are considered to be free of the prior art since the prior art does not teach or fairly suggest an isolated polynucleotide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3, wherein said fragments comprises either of SEQ ID NOs: 3-7 or a sequence that hybridizes after three washes at 65°C in the presence of 0.2x SSC and 0.1% SDS, wherein said polynucleotide in the absence of inverted terminal repeat sequences from adeno-associated virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, wherein the polynucleotide further comprises an expression cassette of SEQ ID NO:9 operably linked to the polynucleotide and the expression cassette further comprises an origin of replication which is active in cardiac cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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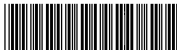
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tcg

February 15, 2008

/Terra Cotta Gibbs/

Application Number**Application/Control No.**

10/802,030

Examiner

TERRA C. GIBBS

**Applicant(s)/Patent under
Reexamination**

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